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272 7590 07/22/2010

SCULLY, SCOTT, MURPHY & PRESSER, P.C.
400 GARDEN CITY PLAZA
SUITE 300
GARDEN CITY, NY 11530

EXAMINER

GOON, SCARLETT Y

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 07/22/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,692	07/05/2005	Olli-Pekka Eromaa	18475	1908

TITLE OF INVENTION: CRYSTALLIZATION OF POLYOL COMPOSITIONS, CRYSTALLINE POLYOL COMPOSITION PRODUCT AND USE THEREOF

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	10/22/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Complete and send this form, together with applicable fee(s), to: **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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272 7590 07/22/2010

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or by facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,692	07/05/2005	Olli-Pekka Erona	18475	1908

TITLE OF INVENTION: CRYSTALLIZATION OF POLYOL COMPOSITIONS, CRYSTALLINE POLYOL COMPOSITION PRODUCT AND USE THEREOF

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nonprovisional	NO	\$1510	\$300	\$0	\$1810	10/22/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
GOON, SCARLETT Y	1623	426-471000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).	2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
<input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.	1_____
<input type="checkbox"/> "Fee Address" indication (or "Fee Address" indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.	2_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE _____ (B) RESIDENCE: (CITY AND STATE OR COUNTRY) _____

Please check the appropriate assignee category or categories (will not be printed on the patent): Individual Corporation or other private group entity Government

4a. The following fee(s) are submitted:	4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)
<input type="checkbox"/> Issue Fee	<input type="checkbox"/> A check is enclosed.
<input type="checkbox"/> Publication Fee (No small entity discount permitted)	<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.
<input type="checkbox"/> Advance Order - # of Copies _____	<input type="checkbox"/> The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)	<input type="checkbox"/> a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.	<input type="checkbox"/> b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).
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NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS; SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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SUITE 300				1623
GARDEN CITY, NY 11530				PAPER NUMBER
DATE MAILED: 07/22/2010				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 262 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 262 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No. 10/517,692	Applicant(s) EROMA ET AL.
	Examiner SCARLETT GOON	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to 7 June 2010.

2. The allowed claim(s) is/are 75-90.

3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of the:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) including changes required by the Notice of Draftperson's Patent Drawing Review (PTO-948) attached
1) hereto or 2) to Paper No./Mail Date _____.

(b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of
Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. Notice of References Cited (PTO-892)

5. Notice of Informal Patent Application

2. Notice of Draftperson's Patent Drawing Review (PTO-948)

6. Interview Summary (PTO-413),
Paper No./Mail Date _____.

3. Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 24 June 2010

7. Examiner's Amendment/Comment

4. Examiner's Comment Regarding Requirement for Deposit
of Biological Material

8. Examiner's Statement of Reasons for Allowance

9. Other _____.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

On 9 July 2010 and 13 July 2010, a proposed amendment in condition for allowance was discussed with Mr. Mark Cohen, Applicants' attorney, in a telephone interview. Authorization for this examiner's amendment was given in a telephone interview with Mr. Mark Cohen on 12 July 2010 and 15 July 2010.

The application has been amended as follows:

- Claims 75, 76, 82 and 83 have been amended as listed below.
- Note: For those claims that are neither amended nor canceled as indicated in this Examiner's Amendment, see the amendment filed on 7 June 2010.

75. (Currently Amended) A process for the microcrystallization of polyols xylitol and maltitol into a polyol composition, comprising the steps of:

(a) spraying a liquid feed of dissolved xylitol and maltitol containing at least 25% 30% by weight of each at the dry solids concentration of 60-90% into contact with a gas suspended dry feed of small crystals containing xylitol and maltitol so as to wet the

surface of said dry feed particles with said liquid feed, wherein the ratio of liquid feed to dry feed is between 2:1 and 1:4;

(b) evaporating the solvent of said liquid feed causing microcrystallization of said dissolved xylitol and maltitol on said dry feed particles and drying in the gas suspended state to a free moisture content of 0.5 – 3%; and

(c) conditioning the microcrystallized particles at a temperature of 40-90°C to provide a solid randomly agglomerated microcrystalline xylitol-maltitol composition with microcrystals of 5-10 micrometers in size, ~~and~~ and a free moisture content of 0.05% - 0.5%, and that which melts at about 90 °C, °C:

wherein the ratio of xylitol and maltitol in said feeds being such that the resulting microcrystalline eutectic mixture contains ~~from 50% to 75% by weight of xylitol and from 25% to 50% by weight maltitol~~ 30% or more of each of xylitol and maltitol microcrystallized together into a solid microcrystalline product:

(d) optionally milling the dried randomly agglomerated microcrystalline polyol composition from step c) to a mean particle size of 0.1 – 0.4 mm.

76. (New) A process according to Claim 75, wherein said liquid feed comprises a solution containing xylitol and maltitol dissolved in water at a total concentration of about 60-90% on DS dry substance (DS).

82. (Currently amended) A process according to any one of Claims 75-81, wherein said liquid feed and/or dry feed contains a minor portion of an excipient, an active or inert ingredient and/or other sweetener other than maltitol, or xylitol or lactitol.

83. (Currently amended) A process according to Claim 75, wherein the dry feed comprises a powder containing core material selected from the group consisting of milled crystals of xylitol and maltitol, milled crystals and/or microcrystals of another polyol, and milled crystals, microcrystals and/or powders of other inert or active ingredient(s), said core material being milled and/or sieved to a particle size of less than 200 µm.

DETAILED ACTION

Claims 75-90 are pending in the instant application and are found to be allowable.

Information Disclosure Statement

The information disclosure statement (IDS) dated 24 June 2010 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. Accordingly, it has been placed in the application file and the information therein has been considered as to the merits.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: Applicants' process for the microcrystallization of xylitol and maltitol into a solid microcrystalline composition, as recited in the instant claims, are not found to be taught or fairly suggested in the prior art, as discussed below. Thus, the claimed method is seen to be novel and non-obvious over the prior art.

Objections Withdrawn

In view of the cancellation of claims 1-74, all objections made with respect to claims 1-74 in the previous Office Action are withdrawn.

These objections have been **withdrawn**.

Rejections Withdrawn

Applicants' amendment and remarks, filed 7 June 2010, with respect to the rejection of claims 58-73 and 75 under 35 USC § 103(a), as being unpatentable over WIPO publication WO 99/59426 to Heikkilä *et al.*, in view of US Patent No. 5,017,400 to Olinger *et al.*, have been fully considered and are persuasive. Applicants argue that although Heikkilä *et al.* teach that microcrystalline xylitol can be microcrystallized with other compounds, Heikkilä *et al.* teach that the xylitol purity of the product is preferably more than 80%, preferably more than 90%, most preferably up to 98% or more. Thus, although one of ordinary skill in the art may have been motivated to include another polyol into the process for microcrystallization of xylitol based on the combined

teachings of Heikkilä *et al.* and Olinger *et al.*, one of ordinary skill in the art would not have been motivated to modify the method of Heikkilä *et al.* to arrive at the instantly claimed invention in which each of the two polyols is present in the resulting composition in 30% or more. This rejection has been withdrawn.

Applicants' amendment and remarks, filed 7 June 2010, with respect to the rejection of claims 58-73 and 75 under 35 USC § 103(a), as being unpatentable over WIPO publication WO 99/59426 to Heikkilä *et al.*, in view of WIPO publication WO 91/07100 to Oravainen *et al.*, have been fully considered and are persuasive. Applicants argue that although Heikkilä *et al.* teach that microcrystalline xylitol can be microcrystallized with other compounds, Heikkilä *et al.* teach that the xylitol purity of the product is preferably more than 80%, preferably more than 90%, most preferably up to 98% or more. Thus, although one of ordinary skill in the art may have been motivated to include another polyol into the process for microcrystallization of xylitol based on the combined teachings of Heikkilä *et al.* and Oravainen *et al.*, one of ordinary skill in the art would not have been motivated to modify the method of Heikkilä *et al.* to arrive at the instantly claimed invention in which each of the two polyols is present in the resulting composition in 30% or more. This rejection has been withdrawn.

In view of the cancellations of claims 1-74, all rejections made with respect to claims 1-74 in the previous Office Actions are withdrawn.

All prior art rejections of record are hereby withdrawn.

Closest Prior Art

The remaining closest prior art to the instantly claimed invention is U.S. Patent No. 6,165,511 to Schwarz *et al.* (hereinafter referred to as the '511 patent; IDS dated 11 February 2005). The Schwarz '511 patent discloses methods for the preparation of compositions consisting essentially of at least two polyols wherein the resulting composition comprises more than 80% of one or more non-hygroscopic polyols, based on the total polyol content (column 2, lines 55-67). Known non-hygroscopic polyols are listed as including mannitol, lactitol, isomaltitol and xylitol (column 1, lines 24-25). Preferably, the polyol composition essentially consists of 85 to 99% by weight, in particular, 88 to 98% by weight, of mannitol, and 5 to 15% by weight, in particular 6 to 12% by weight, of one or two polyols selected from lactitol and sorbitol. The Schwarz '511 patent differs from the instantly claimed invention in that it does not disclose a method and/or composition comprising 30% or more of each of two polyols. While it may be *prima facie* obvious for one of ordinary skill in the art to modify the polyol crystals of the Schwarz '511 patent to a microcrystalline size, for reasons such as to increase the surface area of the crystals for ease in solubilization, the difficulties of crystallizing a single composition comprising two different polyols both present in significant amounts, such as greater than 25%, are well-known in the art. Thus, it would not have been *prima facie* obvious for one of ordinary skill in the art to modify the method disclosed in the Schwarz '511 patent to arrive at the instantly claimed invention wherein the claimed method results in a microcrystalline solid product containing 30%

or more of each of xylitol and maltitol. As such, the instantly claimed invention is not *prima facie* obvious over the teachings of the Schwarz '511 patent.

Methods for the microcrystallization of xylitol and maltitol into a solid composition containing 30% or more of each of the said polyols, is disclosed in the instant Specification. Additionally, the instant Specification illustrates the claimed process in Example 1, which discloses microcrystallization of 50/50 maltitol/xylitol, and Example 3, which discloses microcrystallization of 25/75 maltitol/xylitol. Hence, the instantly claimed processes for the microcrystallization of xylitol and maltitol have sufficient written description in the Specification.

Conclusion

Accordingly, Applicants' amendment and the Examiner's Amendment are sufficient to place the application in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

/SCARLETT GOON/
Examiner
Art Unit 1623